

Appln. No. 10/674,228
Reply to Office action of August 19, 2005
Response dated December 16, 2005

REMARKS

This paper is filed in response to the Office Action dated August 19, 2005. Claims 1-21 are pending in the application. Claims 5-21 have been withdrawn as directed to non-elected subject matter. Claims 1-4 have been rejected.

The Examiner has rejected claims 1-4 under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. In particular, the Examiner states that claim 1 in step (d) recites "antiserum" from a subject, and step (e) recites "serum." Applicants have amended step (d) in claim 1 to replace "antiserum" with "serum." No new matter has been added.

The Examiner has rejected claims 1-4 under 35 U.S.C. 102(b) as anticipated by Hirsch *et al.*, J. CANCER RES. CLIN. ONCOL., 114(2) 204-7 (1988) ("Hirsch *et al.*"). The Examiner alleges that Hirsch *et al.* discloses a method of identifying proteins derived from patients with Hodgkin's disease using the steps of the presently claimed invention.

However, Hirsch *et al.* describes subjecting lysates of Hodgkin's cell line cells to a one-dimensional gel electrophoresis before transferring proteins to nitrocellulose by the Western blot technique, and thereafter testing sera from patients with Hodgkin's disease (HD) for antibody activity. (See page 205, left hand column, lines 2-12). Using this one-dimensional Western blot method a single protein, P-65, was identified to which only a small percentage (26 samples positive, 17%) of the 152 HD patient sera contained antibodies. Moreover, one serum sample from a healthy subject also reacted with P-65. (See page 205, right hand column, paragraph 2). To further characterize P-65,

Appln. No. 10/674,228
Reply to Office action of August 19, 2005
Response dated December 16, 2005

26 antibody positive cancer samples were used in two-dimensional immunoblots to identify the isoelectric point of P-65. "These sera were then used as primary antibodies for two-dimensional immunoblots which allowed further characterization of the depicted polypeptide." (See page 205, left hand column, lines 12-14).

The paper reported that P-65 represents an abundant protein (antigen) in several lymphoid cell lines (Raji, B-95/8, BJA-B), in normal human lymphocytes, and in lymphocytes from patients with chronic lymphocytic leukemia. (See page 205, right hand column, paragraph 1). The authors therefore concluded that "P-65 did not prove to be specific for the HD-related L-428 cells since it was also abundant in a series of other lymphoid cells" (See page 206 right hand column, last paragraph). Thus, "the relationship between antibodies to P-65 and HD is not clear." (See page 207, left hand column, lines 3-4). Consequently, one skilled in the art would not consider an antibody to P-65 sufficiently accurate to diagnose a patient with cancer. This would be further exacerbated by the fact that the P-65 protein can be identified in both tumor-derived and non-tumor cell lines. Accordingly, Hirsch *et al.* does not disclose or suggest a method of identifying proteins as recited in the presently claimed invention.

Furthermore, Hirsch *et al.* only teaches that one should use one-dimensional gel electrophoresis and Western blotting to identify samples containing antibodies, which samples may then be used in two-dimensional immunoblotting to further characterize the depicted polypeptide. Unlike the present invention, Hirsch *et al.* required the prior knowledge gained from one-dimensional electrophoresis to identify P-65, the presence of which is not exclusive to patients with Hodgkin's disease. Thus, two-dimensional

Appln. No. 10/674,228
Reply to Office action of August 19, 2005
Response dated December 16, 2005

electrophoresis was only used to further characterize P-65, which had already been found by one-dimensional electrophoresis. Consequently, Hirsch *et al.* does not disclose the use of two-dimensional electrophoresis to find proteins that had not been found by one-dimensional electrophoresis. Furthermore, Hirsch *et al.* does not disclose the comparison of proteins to which antibodies in the subject serum sample bind, with proteins to which antibodies in a control serum sample bind, to thereby identify proteins to which a subject with cancer produces autoantibodies. Consequently, Hirsch *et al.* does not teach or suggest each and every element of the claimed invention.

In view of the foregoing, reconsideration and withdrawal of the rejection of claims 1-4 under 35 U.S.C. 102(b) as anticipated by Hirsch *et al.* is respectfully requested.

A one-month extension to the time for responding is respectfully requested. Payment of the extension fee is to be made according to the Credit Card Payment Form attached herewith. Applicants believe that no additional fees are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300, referencing Docket Number 108140.00015.

Appln. No. 10/674,228
Reply to Office action of August 19, 2005
Response dated December 16, 2005

In view of the foregoing, Applicants respectfully submit that the pending claims are now in a condition for allowance. Prompt consideration and allowance are therefore respectfully requested.

Respectfully submitted,



Rochelle K. Seide, Ph.D.
Registration No. 32,300
ARENT FOX PLLC
1675 Broadway
New York, NY 10019
Tel. No. (212) 484-3945
Fax No. (212) 484-3990
Customer No. 38485